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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,643	04/20/2001	Gad Keren	1291-01	2139

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EXAMINER

FLYNN, AMANDA R

ART UNIT	PAPER NUMBER
3751	

DATE MAILED: 08/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/839,643	KEREN ET AL.
<b>Examiner</b>	<b>Art Unit</b>	
Amanda R. Flynn	3751	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) 1-20 is/are rejected.  
 7) Claim(s) 19-20 is/are objected to.  
 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 10 January 2002 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.  
 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.  
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.  
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ . | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### ***Drawings***

2. The drawings are objected to because Figure 2 does not show the placement of the shunt, in relation to the pump. Additionally, Figures 3-5 are not discussed in the specification. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Specification***

3. The substitute specification filed November 13, 2001 has not been entered because it does not conform to 37 CFR 1.125(b) because: a marked-up copy of the substitute specification has not been supplied.

4. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

5. The abstract of the disclosure is objected to because of the phrase "The present invention is thus directed" in line 1. Additionally, the length of the abstract should not exceed 150 words. Correction is required. See MPEP § 608.01(b).

6. The use of the trademark Elgiloy® has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

7. The disclosure is objected to because of the following informalities: On page 7, the word "and" should be replaced with the word --an--. On page 8, the word "shon" should be replaced with the word --shown--. On page 10, the word "position" incorrectly appears in plural form. On page 13, the word "hear" should be replaced with the word --heart--.

Appropriate correction is required.

#### *Claim Objections*

8. Claims 19 and 20 are objected to because of the following informalities: Claim 19 references a "tissue affixation element," while claim 20 makes reference to "tissue fixation elements." The examiner requests the consistent use of the appropriate term.

Appropriate correction is required.

#### *Claim Rejections - 35 USC § 112*

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 11 recite the limitation "the cardiac structure" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 recites the limitation "said tubular element" in line 1. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-2 and 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Number 4,705,507 to Boyles.

Boyles shows an arterial catheter, comprising a lumen, which is placed in the left ventricle of the heart, as seen in Figure 1. The catheter permits the shunting of a small volume of blood out of the left ventricle, thereby reducing the diastolic pressure of the heart (col. 3, lines 46-54).

***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3751

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 9 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyles.

Boyles discloses the previously described arterial catheter, further comprising a tubular element 11, as seen in Figure 1. Boyles lacks a teaching of an affixation element located at the ends of the tubular catheter.

The examiner takes official notice that a catheter must be affixed to a specific location in the cardiac structure, to ensure stability of the tubular element.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to produce the disclosed arterial catheter of Boyles, with affixation elements at its ends, to ensure stability and proper direction of blood flow through the device.

15. Claims 3-4, 10 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyles in view of U.S. Patent Number 5,584,803 to Stevens et al.

In regard to claims 3-4 and 13-14, Boyles discloses the previously described arterial catheter, further comprising a check valve 25 "which opens when the heart pumps and then closes thereby restricting blood flow when the heart relaxes (col.2, lines 63-65)," as seen in Figure 3. Boyles shows that the pumping and relaxing motions of the heart create a pressure differential, which allows passive functioning of the valve. Boyles lacks a teaching of preventing the shunting of blood during left ventricular systole, as claimed.

Stevens et al. disclose a system for cardiac procedures comprising a balloon catheter with a flexible tubular shaft, which is positioned adjacent the left ventricle. The shaft of the disclosed device "has a bending stiffness selected to maintain the position of the occluding means against

systolic blood flow from the patient's heart when the occluding means is expanded (col. 9, lines 30-33)," thus preventing shunting during left ventricular systole.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to produce the disclosed arterial catheter of Boyles, with means of preventing left ventricular systole as described by Stevens et al., in order to reduce the end diastolic pressure.

In regard to claim 10, Boyles discloses the previously described arterial catheter, but is silent in regard to the material of composition of the described tubular element.

Stevens et al. disclose that "shaft 322 may be constructed of any of a variety of materials, including biocompatible polymers such as polyurethane, polyvinyl chloride, polyether block amide, or polyethylene (col. 34, lines 7-10)."

It would have been obvious to one having ordinary skill in the art at the time the invention was made to produce the disclosed arterial catheter of Boyles, using a biocompatible material, as disclosed by Stevens et al. to prevent adverse physiological reactions to the material of the catheter.

#### ***Allowable Subject Matter***

16. Claims 5-8, 15-18 and 20 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent Number 5,186,431 to Tamari discloses pressure sensitive valves for extracorporeal circuits, which adjust blood flow as a function of pressure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda R. Flynn whose telephone number is 703-306-4056. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory L. Huson can be reached on 703-308-2580. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-7766 for regular communications and 703-305-7766 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1113.

Amanda R. Flynn  
Examiner  
Art Unit 3751

arf  
August 6, 2002

  
TIMOTHY L. MAUST  
PRIMARY EXAMINER